CENTER FOR DRUG EVALUATION AND RESEARCH

65-005

APPLICATION NUMBER:

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA #: 65-005

FIRM: Global Pharmaceutical Corporation

DRUG PRODUCT: Minocycline Hydrochloride Capsules, USP, 50 mg and 100 mg

DOSAGE: See above **STRENGTH:** See above

CAMP STATEMENT/EIR UPDATE STATUS: ~~Pending~~ Acceptable 2/25/99

BIO STUDY: Acceptable (5/20/98)

METHOD VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S): Not requested (USP drug)

STABILITY - (ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION): The container/closure system used in the stability study is the same as those described in the container section.

LABELING: Acceptable (2/4/99)

STERILIZATION VALIDATION: N/A

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?): See below

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

Two exhibit batches capsules for 50 mg and capsules for 100 mg) are manufactured to support the proposed maximum production batch size capsules) for both 50 mg and 100 mg.

PROPOSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?): See above

Specifications for active ingredient: Under #23A

Specifications for the finished product: Under #28 and #29

CHEMIST: Maria C. Shih 2/22/99 **DATE:** 2/16/99

SUPERVISOR: R. Adams **DATE:**

R.C. Adams 2/22/99

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 65-005

Date of Submission: September 16, 1998

Applicant's Name: Global Pharmaceutical Corporation

Established Name: Minocycline Hydrochloride USP, 50 mg (base) and 100 mg (base)

Labeling Deficiencies:

1. CONTAINER:

   a. 50 mg - 100s

      Satisfactory in final print.

   b. 100 mg - 50s

      Satisfactory in final print.

2. INSERT

   a. DESCRIPTION

      In the first sentence correct the spelling "tetracycline".

   b. CLINICAL PHARMACOLOGY

      i. Second paragraph, second sentence, revise to read, "...compared to...".

      ii. *Microbiology*

         GRAM-NEGATIVE BACTERIA

            Revise the list of gram-negative bacteria so that *Listeria monocytogenes* is listed only once.

      iii. *Susceptibility Tests*

A) *Diffusion Techniques*

Add the following as the last paragraph:

> Standardized procedures require the use of laboratory control organisms. The 30 mcg tetracycline disk should give zone diameters between 19 and 28 mm for *Staphylococcus aureus* ATCC 25923 and between 18 and 25 mm for *Escherichia coli* ATCC 25922. The 30 mcg minocycline disk should give zone diameters between 25 and 30 mm for *S. aureus* ATCC 25923 and between 19 and 25 mm for *E. coli* ATCC 25922.

B) *Dilution Techniques*

Add the following as the last paragraph:

> As with standard diffusion methods, dilution procedures require the use of laboratory control organisms. Standard tetracycline or minocycline powder should give MIC values of 0.25 mcg/mL to 1 mcg/mL for *S. aureus* ATCC 25923, and 1 mcg/mL to 4 mcg/mL for *E. coli* ATCC 25922.

c. DOSAGE AND ADMINISTRATION

i. Make use of italic print when referring to species of bacteria throughout this section.

ii. First sentence of fifth paragraph, revise to read, ...the usual dosage...".

d. HOW SUPPLIED

i. We encourage you to include the NDC numbers.

ii. Relocate the text "Bottles of 100" and "Bottles of 50" to appear after the description each capsule.

Please revise your package insert labeling, as instructed

above, and submit in final print.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research